patients from 2000 to 2007 were matched 1:10 by age and gender to cancer-free controls selected from the PHARMO RLS with date of diagnosis as the index date for both RCC patients and their controls. TE events were defined as any venous TE event or arterial TE event requiring hospitalization in the 12 months before or after index date. **RESULTS:** A total of 973 RCC patients were included, 6% of whom underwent nephrectomy. The proportion of patients with any TE event was similar before (2.0%, 95% CI: 1.2–3.0%) and after (1.4%, 95% CI: 0.8–2.4%) RCC diagnosis. Arterial TE events were more common prior to diagnosis (1.6%, 95% CI: 0.9–2.7%) than post-diagnosis (0.5%, 95% CI: 0.2–1.2%), whereas venous TE events were less common prior to diagnosis (0.3%, 95% CI: 0.1–0.9%) than post-diagnosis (0.9%, 95% CI: 0.4–1.8%). Compared to cancer-free controls, RCC patients were more likely to have had a pre-diagnosis (odds ratio = 2.7, 95% CI: 1.6–4.4) or post-diagnosis (hazard ratio = 2.1, 95% CI: 1.2–3.7) TE event. **CONCLUSIONS:** In this population-based study, RCC patients were twice as likely to develop TE events compared to cancer-free controls, although frequency of events was low. These results emphasize the need for careful observation of RCC patients after diagnosis.

PCN6

A COMPARISON OF CLINICAL EFFICACY AND SAFETY OF LENOGRASTIM AND FILGRASTIM IN THE STEM CELL MOBILIZATION

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OBJECTIVES: TO compare efficacy and safety of lenograstim and filgrastim in stem cell mobilization in healthy donors (allogenic transplantation) and in oncological patients (autologous transplantation). **METHODS:** Comparison was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. The most important medical databases were searched (EMBASE, MEDLINE, CENTRAL). Two reviewers independently selected trials, assessed their quality and extracted data. Meta-analysis of head-to-head trials was performed to compare lenograstim and filgrastim in stem cell mobilization in healthy donors and oncological patients. **RESULTS:** The results of 4 RCTs in healthy donors and 3 RCTs in oncological patients were included in the analysis. For healthy donors mobilization with lenograstim resulted in higher number of CD34+ cells harvested than mobilization with filgrastim (WMD = 0.66×10^6 per kg of body weight [0.05; 1.26]). No differences between lenograstim and filgrastim were found in the number of donors requiring second apheresis (RR = 0.91 [0.62; 1.35]). Adverse events rates were similar in both arms. Most common adverse events including bone pain and arthralgia. For oncological patients no differences in the number of patients that gained target CD34+ cells ($>2 \times 10^6$) were found (RR = 0.72 [0.33; 1.55]). Results for hematological recovery are inconsistent. No significant differences in the incidence of neutropenia were noted (RR = 0.72 [0.50; 1.03]) whereas platelet transfusions were more frequent in filgrastim treated patients than in lenograstim group (RR = 0.16 [0.04; 0.67]). The length of hospital stay after transplantation was similar in both groups. No significant differences regarding safety outcomes were reported. **CONCLUSIONS:** In healthy donors lenograstim is more potent than filgrastim in stem cell mobilization into peripheral blood and no differences in safety profiles between two drugs were noted. In oncological patients both drugs has similar impact on stem cell mobilization while lenograstim dicreases the risk of platelet transfusion. Acknowledgements: **This analysis was supported by** Sanofi-Aventis.

PCN7

A COMPARISON OF CLINICAL EFFICACY AND SAFETY OF PERIPHERAL BLOOD STEM CELL TRANSPLANTATION AFTER MOBILIZATION WITH LENOGRASTIM AND FILGRASTIM

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OBJECTIVES: This study compared efficacy and safety of allogenic peripheral blood stem cell transplantation (PBSCT) after mobilization with either lenograstim or filgrastim. **METHODS:** Comparison was based on randomized controlled trials (RCT) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. The most important medical databases were searched (EMBASE, MEDLINE, CENTRAL). Two reviewers independently selected trials, assessed their quality and extracted data. Since head-to-head trials were not found, indirect comparison using Bucher's method was performed. **RESULTS:** The results of 2 RCTs for PBSCT after lenograstim mobilization and 7 for PBSCT with filgrastim were included. In all trials PBSCT was compared with bone marrow transplantation (BMT). No significant differences between lenograstim and filgrastim were found in mortality rate (RR = 0.84 [0.49; 1.42]) and relapse rate (RR = 0.69 [0.19; 2.49]). PBSCT after mobilization with lenograstim comparing to BMT does not increase the risk of acute graft versus host disease (GvHD) (RR = 1.06 [0.73; 1.53]) whereas PBSCT after filgrastim use is associated with higher risk of acute GvHD than BMT (RR = 1.19 [1.03; 1.37]). However indirect comparison results in similar incidence of acute GvHD (RR = 0.89 [0.60; 1.32]. The was also no difference between lenograstim and filgrastim in respect to chronic GvHD (RR = 1.33 [0.84; 2.11]. Lenograstim and filgrastim in PBSCT resulted in similar mortality rate due to GvHD (RR = 0.55 [0.19; 1.59]), treatement realted mortality (RR = 1.11 [0.60; 2.04]). No differences in hospital admissions for donors mobilized with lenograstim and filgrastim were identified (RR = 1.04 [0.60; 1.79]). **CONCLUSIONS:** Indirect comparisons indicate similar efficacy and safety of PBSCT after mobilization with lenograstim and PBSCT after mobilization with filgrastim. Acknowledgements: **This analysis was supported by** Sanofi-Aventis.

PCN8

COMORBIDITIES IN PATIENTS WITH METASTATIC COLORECTAL CANCER

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OBJECTIVES: To describe the prevalence of comorbidities in the newly diagnosed mCRC population. **METHODS:** The study used a large US claims database. Patients aged ≥18 with newly diagnosed mCRC between January 2005 and June 2008 were selected using the ICD-9 diagnosis codes (CRC: 153.x [excluding 153.5], 154.0, 154.1, 154.8; distant metastasis: 196.0, 196.1, 196.3, 196.5, 197.x (excluding 197.5), 198, 199.0). The initial mCRC diagnosis date was defined as the index date. One-year continuous medical and drug benefit coverage prior to the index date was required. Medical diagnoses and medication treatments were examined. All comorbidities were estimated during 1-year except for traumatic conditions which were assessed for 30-day prior to the index date. **RESULTS:** Based on the selection criteria, 12,648 patients were included with mean (±standard deviation) age of 66.3 (±13.0) years, 54% male, and 70% with colon primary. Distribution of metastases included liver (40%), lung (14%), bone (6%), and brain (3%). The most prevalent comorbidity was cardiovascular disease (CVD) (62% of patients) including hypertension (41%), coronary artery disease (17%), congestive heart failure (7%), dysrhythmias (14%), arterial thromboembolism including ischemic heart disease (18.6%), and venous thromboembolism (6%). Over 10% of patients had a major surgery, bone fracture, or open wound 30 days prior to mCRC diagnosis; 31% had a history of bleeding; and nearly 12% of patients were treated with anticoagulant and 6% with antiplatelet agents. Additionally, 19% of patients had diabetes, 8% had renal failure or insufficiency, and 5% had skin disorders. Patients ≥65 years old had a significantly higher CVD prevalence (73%; $p < 0.001$). **CONCLUSIONS:** Comorbid medical conditions are common in patients with mCRC. CVD is the most prevalent comorbidity and affects approximately ¾ of patients over age 65. It is important to assess comorbidities in all patients with mCRC since their presence may impact treatment decision making.

PCN9

DEVELOPMENT OF SERUM TESTS FOR COLORECTAL CANCER SCREENING

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OBJECTIVES: Current options for colorectal cancer (CRC) screening include imaging procedures such as colonoscopy and flexible sigmoidoscopy, guaiac fecal occult blood tests (gFOBT), and fecal immunochemical tests (FIT). Compliance with screening for CRC guidelines remains low among average-risk adults, at least partly because of low patient acceptance of available tests due to their invasiveness, inconvenience, and perceived safety risks. Serum tests are noninvasive, convenient, and safe, and may improve compliance. We systematically reviewed the literature to assess the current status of serum tests and other screening tests for CRC. **METHODS:** We analyzed studies of CRC screening tests identified in a search of English-language MEDLINE-indexed articles published in the 3 years prior to March 2009 and non-MEDLINE-indexed sources such as organization websites, meeting abstracts, and government publications. **RESULTS:** We identified 123 primary studies from MEDLINE and 45 from non-MEDLINE sources for a total of 168 pertaining to tests or biomarkers for early diagnosis of CRC. Serum biomarkers being evaluated include tumor associated antigens, cytokines, anti-apoptotic and pro-growth factors, and hypermethylated DNA. Biomarkers under development have significantly higher sensitivity for CRC than for adenomatous polyps, making them more effective for cancer detection than prevention. CRC sensitivity and specificity of certain serum biomarkers and serum biomarker panels under development are better than those of the existing test gFOBT and equivalent or better than those of FIT. However, most biomarkers in development are common to other cancers and diseases, reducing their specificity for CRC. **CONCLUSIONS:** Several serum biomarkers show promise in detecting CRC, but require testing in large, average-risk populations. Unless biomarkers are identified that are more specific for adenomas and/or CRC than currently known, and because of the heterogeneity of CRC, the approach most likely to be successful would involve the combination of multiple serum biomarkers to create a distinctive CRC biomarker profile.

PCN10

MALIGNANT GASTROINTESTINAL STROMAL TUMORS TREATED WITH IMATINIB IN FRANCE: EFFICACY IN REAL LIFE

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OBJECTIVES: GISTs are rare tumors of the GI tract. In France, their incidence is estimated to be 9–12/10^6 inhabitants/year. Imatinib has been approved to treat unresectable and/or metastatic Kit-positive GISTs since 2002, but information on routine use, safety and efficacy in unselected "real life" setting is lacking. An observational cohort (EPIGIST) in France was designed to provide data on survival, safety and treatment patterns and quality of life. **METHODS:** EPIGIST is a nationwide

multi-center, observational study on GIST patients treated with Imatinib between the availability on the French Market and the end of the 2008. Centers were randomly selected in national files of oncologists, gastrointestinal surgeons and specialists. The planned follow-up duration was three years. A case report form had to be completed at inclusion and during each follow-up visits. Quality of life was assessed using QLQ-C30 and SF36 questionnaires. **RESULTS:** Thirty on 51 selected centers enrolled at least one patient and 139 patients were included (as of June 2009). The median age of disease onset was 58 years (range 21–86). 42% were metastatic at diagnosis. Primary tumors were most often stomach (48%), or bowel (34%). At diagnosis 86% of patients had a tumor size over 5 cm. 68% of patients had surgery of the primary tumor before starting Imatinib. 68% of patients were considered as high risk of relapse according the Miettinen classification. For 99% of the patients, Imatinib was given at an initial dosage of 400 mg, 1% at 300 mg. Compliance was superior to 90% for 99% of patients. With a median follow-up of 2.1 years, two-years overall survival from first treatment with Imatinib was 83.9% (CI95%: [74.5%–90.1%]). **CONCLUSIONS:** EPIGIST is still an ongoing survey. Current results confirm previous published data on survival in GIST treated with Imatinib in an unselected cohort of patients outside of a clinical trial.

PCN11

INDIRECT COMPARISON TO ESTIMATE THE EFFICACY OF INTERVENTIONS IN TREATMENT OF METASTATIC RENAL CELL CARCINOMA: A MIXED TREATMENT COMPARISON

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OBJECTIVES: The purpose of the study was to evaluate the relative efficacy of different medication interventions in the treatment of metastatic renal cell carcinoma (mRCC) using a Bayesian mixed treatment comparison (MTC) model. **METHODS:** A systemic review was undertaken to identify randomized controlled trials assessing the efficacy of bevacizumab, sorafenib, sunitinib, temsirolimus, and everolimus as stand alone therapy or in combination with interferon Alfa. The search was conducted within seven electronic data bases (CinAhl, AMED, Cochrane Library, Embase, Medline, ASCO, and Clinical trials.gov) for English language publications from inception to June 6th 2009. The Progression Free Survival (PFS) was outcome of interest in this study. Bayesian MTC was performed for evidence synthesis using both fixed and random effect models. With MTC, the relative treatment effect of one intervention compared with another can be obtained in the absence of head-to-head evidence. **RESULTS:** Sunitinib yielded an effect size of 0.75 (95% credible interval: 0.61–0.93) compared to bevacizumab+interferon; 0.43 (0.31–0.75) compared to bevacizumab; 0.54 (0.37–0.85) compared to sorafenib; 0.74 (0.57–0.96) compared to temsirolimus; and 0.97 (0.57–1.57) compared to everolimus. **CONCLUSIONS:** The relative efficacy of sunitinib was better than all medication interventions on PFS except everolimus in the treatment of mRCC.

PCN12

EXPLORING THE ROLE OF OUTCOMES RESEARCH IN DUTCH REIMBURSEMENT POLICY: REAL-WORLD PHARMACOECONOMICS OF OXALIPLATIN IN STAGE III COLON CANCER

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OBJECTIVES: In the Netherlands, additional funding of expensive hospital drugs requires an assessment of real-world cost-effectiveness within 3 years after implementing. We explored the use and limitations of real-world data for the economic evaluation of oxaliplatin plus standard adjuvant treatment in stage III colon cancer. **METHODS:** Real-world data were gathered from the Dutch population-based Cancer Registry supplemented with data from medical records. Patients additionally treated with oxaliplatin (N = 101) were compared to patients receiving only standard adjuvant therapy (N = 105). Moreover, comparisons were made between our findings and results from the randomised controlled trial (RCT) that demonstrated a significantly improved disease-free survival with oxaliplatin, on which current Dutch treatment guidelines are based. **RESULTS:** Patients receiving oxaliplatin are significantly younger and have fewer comorbidities than patients receiving alternative chemotherapy. Median follow-up time of the study was 26.6 months. The adjusted hazard ratio for disease-free survival of 0.84 indicated that oxaliplatin was more effective. However, the 95% confidence interval of 0.35–2.03 revealed large uncertainty about the actual effectiveness in daily clinical practice. Moreover, residual confounding could not be ruled out. On the other hand, patient characteristics, treatment patterns, comparator arm, dosages, toxicities, resource use, costs and disease-free survival outcomes obtained in clinical daily practice showed great similarities with the RCT based data and results. During our study, extended 6-year RCT follow-up results became available which confirmed previous findings. **CONCLUSIONS:** Insight into patient characteristics, treatment patterns, dosage and toxicities observed in daily clinical practice is very useful in determining the extent to which RCT results are generalisable to a real-world setting. However, outcomes research alone does not necessarily lead to internally valid and precise estimates of effectiveness and cost-effectiveness. In these situations, assessment of real-world cost-effectiveness should be based on a careful synthesis of RCT results and real-world observations.

PCN13

A COMPARATIVE EFFECTIVENESS ASSESSMENT OF FIRST-LINE BEVACIZUMAB + INTERFERON ALPHA-2A VS SUNITINIB IN METASTATIC RENAL CELL CARCINOMA

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OBJECTIVES: Bevacizumab (BEV) + Interferon-alpha-2a (IFN-α) and sunitinib (SUN) have shown significant increase in progression free survival (PFS) compared to IFN-α in first-line metastatic renal cell carcinoma (mRCC) therapy. There is no head-to-head evidence available comparing both regimens, however there is an increasing need to assess and compare the relative efficacy and effectiveness of both therapy approaches. **METHODS:** We applied the widely accepted indirect comparison method (Bucher et al. *J Clin Epidemiol* 1997) to PFS data of the pivotal phase III trials, that is, the unadjusted investigator-assessed PFS hazard ratios (HR) for BEV+IFN-α vs. IFN-α (0.63) and for SUN vs IFN-α (0.52). To enable valid indirect comparison, the IFN-α control arms of both trials have been standardised by recalculating the indirect HR and transferring them into direct HR estimates using the cross-trial proportions. In addition, we adjusted for effects of down-dosing and patient compliance based on published evidence. Sensitivity analyses on adjustment components have been performed. **RESULTS:** The unadjusted indirect efficacy comparison resulted in a statistically non-significant PFS difference of SUN vs BEV+IFN-α (HR: 0.82; 95% CI: 0.64–1.06; p = 0.13). Standardising the IFN arms and simulating realistic scenarios for SUN down-dosing and patient compliance results in similar PFS HRs for BEV+IFN-α (HR: 0.63) and Sunitinib (HR: 0.64) as compared to IFN alone. The adjusted indirect PFS HR of SUN vs BEV + IFN-α was 1.025 (95% CI: 0.81–1.30; p = 0.83). Results were mostly influenced by IFN-α control arm adjustment, followed by patient compliance and down-dosing. **CONCLUSIONS:** Based on our comparative effectiveness evaluation in first-line mRCC therapy, there is no statistically significant evidence for a difference in efficacy and effectiveness regarding PFS between BEV+IFN-α and SUN. These findings imply that additional treatment decision criteria such as tolerability need to be considered to guide treatment decisions.

PCN14

AN INDIRECT COMPARISON OF THE EFFICACY OF BEVACIZUMAB PLUS CISPLATIN AND GEMCITABINE (BCG) OR BEVACIZUMAB PLUS CARBOPLATIN AND PACLITAXEL (BCP) VERSUS CETUXIMAB PLUS VINORELBINE AND CISPLATIN (CVC) IN PATIENTS WITH ADVANCED OR RECURRENT NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC)

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OBJECTIVES: New treatment options are needed for advanced NSCLC offering improved progression-free (PFS) and overall survival (OS) over standard chemotherapy. Bevacizumab, a humanised monoclonal antibody (MAb) against VEGF, plus chemotherapy increases PFS and OS in advanced NSCLC patients versus chemotherapy alone[4–5]. Cetuximab, a MAb targeting EGFR, showed significant OS when combined with chemotherapy[3]. This study compared the clinical benefits for NSCLC patients treated with BCG or BCP to CVC using indirect treatment comparison (ITC) methodology. **METHODS:** In the absence of head-to-head trials, ITC[1–2] was performed on patients with non-squamous NSCLC comparing the relative benefit of first-line therapies BCG/BCP versus CVC by hazard ratios (HR) adjusted for differences in underlying chemotherapy and populations. Where HRs were not reported, HRs[1] and standard errors[6] were estimated. Based on the ITC a statistical disease model was developed to estimate the adjusted time in PFS and OS. **RESULTS:** ITC-estimated HRs for the primary endpoints in AVAiL[4] and E4599[5] showed that the adjusted PFS HR for BCG versus CVC was 0.80 resulting in an expected time spent in PFS for BCG of 9.62 versus 7.99 months for CVC. Model-derived data showed BCP treatment in patients with adenocarcinoma histology resulted in adjusted BCP HR of 0.89 versus CVC. Model data also showed that BCP patients experienced on average, 19.55 versus. 17.57 months (CVC) of OS. Sensitivity analyses confirmed the robustness of these findings. **CONCLUSIONS:** Interpretation of ITC findings are limited due to cross-study heterogeneity. However results show that BCG or BCP therapy in patients with advanced non-squamous NSCLC brings a superior benefit in terms of OS and PFS compared with CVC therapy.